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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/844,336	04/18/1997	PAMELA R. CONTAG	8678-004-999	7227

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ROBINS & PASTERNAK LLP
1731 EMBARCADERO ROAD
SUITE 230
PALO ALTO, CA 94303

EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	08/844,336	CONTAG ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9,21,22 and 25-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-9,21,22 and 27* is/are rejected.

7)☒ Claim(s) *25 and 26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed on 10-26-2006 are acknowledged. Claims 1, 7, 21 and 25 have been amended. Claims 1, 3-9, 21-22 and 25-27 are pending and currently under examination.

Claim Rejections Withdrawn

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the term "derivative thereof" is withdrawn in light of the amendment thereto.

The rejection of claim 7 under 35 U.S.C. 112, second paragraph, for lacking antecedent basis for the limitation "said intracellular signal transforming domain" in lines 1 and 2 is withdrawn in light of the amendment thereto.

The rejection of claim 21 under 35 U.S.C. 112, second paragraph, for lacking antecedent basis for the limitation "said signal transforming domain" in line 1 and 2 is withdrawn in light of the amendment thereto.

The rejection of claim 25 under 35 U.S.C. 112, second paragraph, for lacking antecedent basis for the limitation "said enzyme signal transforming domain" in lines 1 and 2 is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1, 3-9 21, 22 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menzel et al. (U.S. Patent 5,521,066) in view of Georgiou et al. (U.S. Patent 5,348,867 – IDS filed on 1-22-99) is maintained for reasons of record.

Applicant argues:

1. As acknowledged by the Office, Menzel fails to teach a fusion protein having an extracellular antibody domain.

2. Menzel's system is based on dimerization, the ligand domain is optional and expression of the reporter gene is linked to dimmer formation not ligand binding.

3. Menzel does not teach or suggest a biodetector in which the extracellular domain is an antibody which binds to a ligand and wherein said binding triggers the expression of a reporter gene.

4. There is no transducer in Menzel's system.

5. There is no motive to substitute Georgiou's scFv antibodies for Menzel's dimerization domain or ligand binding domain, because such substitutions would destroy the intended function of Menzel's system.

Applicant's arguments have been fully considered and deemed non-persuasive.

The instant claims are drawn to a biodetector comprising a transmembrane fusion protein comprising an extracellular ligand-specific moiety comprising an antibody and an intracellular enzymatic signal-transforming domain (i.e. signal-converting element); a transducer and a responsive element (transcription activation element) optionally coupled to a reporter gene (luciferase) via said responsive element. Said biodetector may further comprise a bacterial cell.

With regard to Points 2, 3 and 5, Menzel discloses that "a variety of ligand-binding domains" could be used (see column 2, lines 15-16). Moreover, contrary Applicant's assertion, the use of antibodies would not render Menzel's system inoperative. Menzel discloses that the "dimerization domain" (i.e. ligand binding domain) can be anything capable of forming a dimer (see column 4, lines32-36). Since certain antibody classes (e.g. IgA) can form dimmers they meet the requirements set forth by Menzel.

With regard to Point 4, the instant claims merely require a component that changes from an inactive to an active form in response to ligand binding and that that "change" activates a responsive element resulting in a detectable signal. As Menzel discloses the cytoplasmic domain of the wildtype or toxR fusion protein induces binding (via a conformational change) to the promoter region (i.e. the transcription activation element) of the reporter gene (resulting in the expression of the reporter gene) in response to ligand binding to the ligand-binding domain of

said fusion protein, the disclosure of Menzel meets the requirements of the instant claims with regard to the transducer.

As outlined previously, Menzel et al. disclose host cells a transmembrane fusion protein comprising a ligand binding domain, a cytoplasmic toxR DNA binding region, a hydrophobic ToxR transmembrane region and a reporter gene operatively linked to the ctx operon (see column 1, line 65 to column 2, line 6). Menzel et al. further disclose that when a ligand binds to the ligand binding domain, the cytoplasmic domain of the fusion protein to undergo a conformational change which induces binding to the promoter region of the reporter gene (see column 2, lines 35-44). Finally, Menzel et al. disclose that their fusion protein can be used to generate signal using a variety of ligand-binding domains (see column 2, lines 15-16) and that any reporter gene known in the art can be used with the disclosed fusion protein (see column 4, lines 38-42) and that the disclosed fusion proteins can be expressed in bacterial hosts (see column 7, lines 7-8).

Menzel et al. differs from the claimed invention in that they do not explicitly disclose the use of the antibodies or derivatives thereof or the specific use of luciferase as the reporter.

Georgiou et al. disclose methods for the recombinant expression of heterologous proteins on the surface of bacteria (see abstract) including the expression of scFv (see column 6, lines 25-26).

Since Menzel et al. disclose that a variety of ligand binding domains can be used in their transmembrane fusion protein, it would have been obvious to one of skill in the art to use the heterologous scFv disclosed by Georgiou et al. in order to take advantage of the increase in

specificity, diversity and ease of production associated with the resulting fusion protein (biodetector).

Conclusion

Claims 1, 3-9, 21-22 and 27 are rejected.

Claims 25-26 are objected to for being dependent on a rejected claim.

Claims 25-26 are free of the art of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ROBERT A. ZEMAN
PRIMARY EXAMINER

January 5, 2007